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ESTIMATING THE DRINKING WATER COMPONENT OF A DIETARY EXPOSURE ASSESSMENT

OFFICE OF PESTICIDE PROGRAMS
ENVIRONMENTAL PROTECTION AGENCY
(November 2, 1999)

I. EXECUTIVE SUMMARY

The Office of Pesticide Programs (OPP), EPA, is issuing a revised science policy paper to describe changes in its approach to estimate pesticide concentrations in drinking water as part of its assessment of dietary exposures to pesticides. This document was developed from the Agency's science policy paper entitled *Science Policy 5: Estimating the Drinking Water Component of a Dietary Exposure Assessment (12/22/98 Draft)*, that was released for public comment on January 4, 1999 (64 FR 162). The Agency received comments from various organizations. Each of the commentors offered recommendations for improving the science policy. All comments were extensively evaluated and considered by the Agency. This revised version embodies many recommendations of the commentors, as well as recommendations from a May 1999 FIFRA Scientific Advisory Panel which evaluated the proposed approach for incorporating a "crop area adjustment factor" along with a drinking water reservoir scenario in the Agency's surface water screening models. The public comments, as well as a detailed summary of the Agency's response to the comments are also available in the docket for this notice.

For some time the Agency has been using screening models to estimate pesticide concentrations in ground water and surface water to identify those food-use pesticides that are not expected to contribute enough exposure via drinking water to result in unacceptable levels of aggregate risk. The Agency uses monitoring data, where available and reliable, to refine its assessments in those cases where the use of the screening models does not result in "clearing" the pesticide (i.e., indicates a low risk) from a drinking water perspective. This paper's description of the models and approaches EPA generally intends to follow is not meant to restrict interested parties from commenting on the appropriateness of these models and approaches, either generally or in regard to a specific application, or from proposing new or different models or approaches.

In response to public comments, OPP made a number of significant changes to its drinking water assessment approaches, primarily to refine existing screening methods for identifying pesticides which may be present in drinking water at levels of concern. These refinements will enable OPP to more accurately determine whether a pesticide has the potential to result in significant risks to the public and sensitive populations such as infants and children. Specifically, in 1999, OPP will change its screening level drinking water assessment by replacing the "farm field pond" scenario in its surface water screening models with a "drinking water reservoir" scenario and will begin incorporating into the model a factor to account for the area surrounding the reservoir that is cropped. To start, percent cropped area factors will be used for corn, soybeans, cotton, and wheat. Additional factors for other major crops will be added in late 1999 and early 2000. These changes, which better represent actual drinking water conditions, will improve the accuracy of EPA's initial screening assessment. The Agency is also evaluating several watershed-scale surface water models for use in future drinking water assessments.

EPA will continue to use SCI-GROW (Screening Concentration In GROund Water) as an initial screening model for ground water sources of drinking water. An evaluation of models and procedures for a second-tier assessment of pesticide exposure in ground water is beginning. In the meantime, the Agency will rely on ground water monitoring studies to estimate concentrations in ground water for those pesticides which do not pass through the SCI-GROW screen.

The Agency believes its risk assessments would be strengthened by additional monitoring data and is working on a number of levels to fill in the gaps in monitoring data and acquire more high quality data on pesticide concentrations in drinking water sources. Efforts include requesting monitoring and runoff studies on individual pesticides, working with the U.S. Geological Survey (USGS) to obtain more regional- and national-scale monitoring data on multiple pesticides, and exploring design considerations for a national survey of pesticides in drinking water with various government agencies and industry groups and associations.

As a result of the comments, OPP has identified two issues regarding drinking water that will be addressed in separate science policy papers within the next six months. In an effort to better estimate pesticide concentrations in tap water, the Agency will issue a paper on the effectiveness of water treatment in reducing pesticide levels in drinking water and an approach for addressing treatment issues in the assessment process. EPA also plans to issue for public comment a paper on approaches for utilizing available data and models to develop quantitative estimates of pesticide concentrations in drinking water and estimates of people exposed for pesticides which pose a particularly high potential for contaminating drinking water.

II. BACKGROUND

A. Why is EPA concerned about including exposure to pesticides in drinking water in its decisions about acceptable levels of pesticides on food?

With the passage of the Food Quality Protection Act (FQPA) in August 1996, Congress directed EPA to consider "all anticipated dietary exposures and all other exposures for which there is reliable information" in determining whether pesticide residues in food are safe. EPA considers drinking water to be an anticipated dietary exposure route for certain pesticides. Because a number of pesticides have been found in ground water and surface water throughout the United States, EPA will continue to address pesticide exposure through drinking water in the aggregate exposure assessment process. The picture emerging from available federal, state and local water monitoring efforts is complex. Typically, a mix of pesticides is detected in water at low levels with seasonal pulses of higher concentrations. Of the major sources of monitoring data that OPP routinely uses – the United States Geological Survey's (USGS) National Water Quality Assessment Program (NAWQA), Toxic Substances Hydrology Program (TSHP), and National Stream Quality Accounting Network (NASQAN); and the EPA's National Pesticide survey – a majority of the streams (up to 95 percent) and half of the wells near agricultural and urban areas contain detectable levels of at least one, and often two or more, pesticides. Most ground water aquifers and half of the streams investigated by these programs are direct sources of drinking water.

Prior to FQPA, OPP's strategy for managing pesticides which had the potential to contaminate water was to emphasize prevention – requiring mitigation measures such as geographic restrictions on pesticide use and "buffer zones" near water bodies where pesticide use is prohibited. Since FQPA, OPP has routinely assessed exposure to pesticides in drinking water as a part of its dietary risk assessments process.

B. What has been EPA's general process since the passage of the FQPA for including drinking water exposure in its decisions about acceptable levels of pesticides on food?

August 1996-November 1997

While it developed a more science-based policy for estimating drinking water exposure and for interpreting available monitoring data in the initial months after the enactment of FQPA, OPP used an interim approach which assumed that up to 10% of what it considered acceptable exposure to a pesticide could occur via the drinking water route (PR Notice 97-1). Therefore, OPP reserved 10% of the "reference dose[1]" for drinking water related risks and allowed food residues and other routes of exposure to consume no more than 90% of the reference dose. This 10% value for drinking water was a default assumption that OPP knew was likely to overestimate actual exposure in many cases, while potentially underestimating actual exposures in some others.

Overview of EPA's Approach Since November 1997

In November of 1997, OPP ceased using the 10% default assumption and formally adopted the following interim process for addressing drinking water exposures for all pesticides with outdoor uses.

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[1] EPA uses a "reference dose" concept to represent the sum of exposures from dietary and non-dietary sources that, together, do not exceed a maximum safe daily intake. Each source of pesticide exposure (food, residential exposure, and drinking water for each pesticide use) creates a risk that consumes part of the reference dose. The reference dose for a pesticide may allow for a number of crop-specific uses as long as the aggregate exposure and risk from all of those uses do not exceed the maximum safe daily intake. Reference doses have been established for short-term exposure (days to weeks), as well as for lifetime exposure.

1. OPP scientists review all available laboratory and field data submitted by the registrant to determine whether a particular pesticide will easily move to ground water or surface water, will degrade quickly or persist, and will form toxic breakdown products as it degrades.

2. OPP uses pesticide-specific data from these studies in mathematical screening models to estimate pesticide concentrations in water in pesticide use areas. Peer reviews of these models (section II.C.) generally support OPP's view that the estimates coming out of these models are high-end estimates[2] of potential pesticide concentrations in drinking water derived from the upper regions of major watersheds.

3. OPP compares the screening estimates to human health-based "drinking water levels of comparison" (DWLOC)[3], which are derived after first considering all food-related and residential exposures for which EPA has reliable information. Specifically, OPP compares the estimated potential daily intake of pesticide residues by a 10-kg child (age 12 months) consuming 1 liter of water per day (approximates 90th percentile) and by a 70-kg adult consuming 2 liters of water (approximates 80th percentile) per day to the daily intake that would be permitted by the DWLOC.[4] This comparison determines whether OPP clears the pesticide from a drinking water perspective or attempts to refine its estimates of pesticide concentrations in drinking water to reflect more representative and realistic conditions. In some cases, the DWLOC may be very low, not because the pesticide is particularly toxic, but because contributions from food-related uses and other pathways of exposure are so great that very little of the reference dose or target exposure is available to allow for any exposure via drinking water. Alternatively, some pesticides (particularly

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[2] "High-end" refers to a combination of events and conditions such that, taken together, produces conceivable risk to greater than 90 percent of the population subject to the risk assessment, but less than the maximally exposed population. "High-end" is defined in "Guidelines for Exposure Assessment," FRN Vol. 57, No. 104, Fri, May 29, 1992, and "Guidance on Risk Characterization for Risk Managers and Risk Assessors," F. Henry Habicht II, Deputy Administrator, U.S. EPA, to Assistant and Regional Administrators, U.S. EPA, Feb. 26, 1992.

[3] The Drinking Water Level of Comparison (DWLOC) is the theoretical concentration of a chemical in drinking water that would be acceptable as an upper limit in light of *total* aggregate exposure to that chemical from food, water, and non-occupational (residential) sources. It is based on the difference between the maximum daily intake (the reference dose) and the sum of the exposure from food and residential sources. OPP originally used the term "Drinking Water Level of Concern," but felt that this term conveyed more regulatory significance than is intended. The DWLOC is not a regulatory standard for drinking water, but is the theoretical upper limit of "acceptable" exposure after considering food and residential exposures as sources.

[4] To assure the protection of infants/children and adults, and to assure consistency across the Agency, OPP has adopted the same assumptions (bodyweights, daily intakes and the percentiles of consumption for children and adults) that are used by EPA's Office of Drinking Water in setting national drinking water standards. Source: "Exposure Factors Handbook, Vol. 1, General Factors," August, 1997, Office of Research and Development, EPA/600/P-95/002Fa.

newer pesticides) may have a very high DWLOC solely because they have very few food uses or other uses which result in exposure, leaving the majority of the reference dose available for exposures through drinking water. If additional uses are added for a pesticide, the DWLOC will decrease in relation to the exposure added from the new uses.

4. In those instances where the model estimates suggest a potential for concern (i.e., estimated exposure exceeds the DWLOC), additional steps taken by the Agency are determined on a case-by-case basis, depending on how much monitoring data are available and the extent of available information on use and management practices, which are pesticide-specific. These additional steps focus on gathering more information to reduce the uncertainty in the drinking water estimates, analyzing and evaluating existing monitoring data, or requesting additional monitoring data that can be related to drinking water sources.

5. If monitoring data are not available or are not sufficient for purposes of refining the screening level estimates, OPP will first attempt to reduce the uncertainty in screening model estimates by requesting additional pesticide fate data to fill in any gaps in the model inputs. The Agency also evaluates pesticide usage data in relation to potential drinking water sources to determine the potential for a pesticide to reach drinking water. Such refinements would be used to determine whether ground water and/or surface water monitoring is needed. Generally, OPP does not base significant risk management action (e.g., revocation or denial of a tolerance) solely on screening model estimates. However, OPP uses screening models to judge the effectiveness of management options that may be taken to reduce potential exposures to drinking water.

6. If sufficient and reliable monitoring data are available, OPP scientists analyze the data and consult with risk managers as to how the data fit specific risk endpoints being addressed in the human health risk assessment. The Agency evaluates the monitoring data in relation to accompanying information on spatial and temporal distribution of the sample points, the water body (or bodies) represented by the sampling, the characteristics of the site surrounding the water body, and the weather/environmental conditions represented by the study. EPA also attempts to determine whether the sampled water bodies represent real or likely drinking water sources and whether the data represent potentially vulnerable sites. If the evaluation indicates that the data represent drinking water sources, then such data may be used quantitatively in aggregate exposure assessments. Appropriate short-term (for acute effects) and/or longer-term average (for chronic effects or cancer) drinking water concentrations are selected. In keeping with the Agency definition of "high-end" exposure estimates (refer to footnote 2), the Agency selects a "high-end" value, but not necessarily the highest monitoring data value, for use in its risk assessments. The values from monitoring data used in the human health risk assessment are usually less than the model estimates but, in a few cases, may be greater than that predicted by OPP's screening models.

7. Estimates of pesticide concentrations in drinking water, derived from monitoring data, are combined with estimates of water consumption to estimate human exposure via drinking

water. This estimate of exposure is then added to estimates of food and residential exposure to complete the aggregate exposure assessment.

8. If sufficient to do so, the monitoring data may be used to produce a regionally-based picture of the distribution of measurements. However, this is rarely possible due to the variability and uncertainty associated with existing monitoring data and the lack of an extensive monitoring data base for most pesticides.

C. EPA's Use of Screening Models to Estimate Pesticide Concentrations in Drinking Water

1. Surface Water Screening Models

OPP uses two mathematical screening models to assess whether pesticides are likely or unlikely to occur at significant levels in drinking water derived from surface water[5]. The model GENEEC (GENeric Estimated Environmental Concentrations) provides an initial screening level assessment of pesticide concentrations in surface water while the linked Pesticide Root Zone Model (PRZM) and EXposure Analysis Model System (EXAMS) models provide a more refined screen. GENEEC and PRZM/EXAMS, initially used by OPP for ecological risk assessments, are the only mechanistic models available to OPP for rapidly and cost-effectively producing "high-end" estimates of pesticide levels in surface water.

GENEEC uses readily-available pesticide properties to estimate peak and time-averaged pesticide concentrations in a "field pond," 20 million liters (5.3 million gallons) in capacity, located at the edge of a 10-hectare (approximately 25 acres) treated cotton field. The GENEEC model assumes that no buffer exists between the pond and the treated field, that runoff exactly equals water losses due to evaporation, and that the pesticide is uniformly mixed throughout the water body. The model is likely to overestimate pesticide concentrations in drinking water because it is designed to represent a water body in the upper reaches of the watershed while drinking water intakes are typically found lower in the watershed and receive drainage from a greater land area. Pesticide concentrations in water bodies in the upper reaches of agricultural watersheds are generally greater because there may be less dilution from non-agricultural runoff. For this reason, screening model estimates have generally been considered to be "bounding" estimates for drinking water for the purpose of comparison to a DWLOC. GENEEC simulates a single pesticide application or series of applications to bare soil followed by a single rainfall event two days after the final application. Depending on the propensity of the pesticide to move into water or stay with the soil, this storm will wash up to 10% of the pesticide remaining in the top inch of soil at the time of the storm into the pond.

If the surface water estimates using GENEEC do not exceed the DWLOC, then OPP concludes that the pesticide is not expected to pose an unacceptable risk from combined food and

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[5] For a more detailed description of these screening models and their use in the drinking water assessments, see the SAP documents (1997 and 1998) listed in the bibliography.

drinking water exposure as a consequence of runoff into surface water and no further evaluation of surface water exposure is necessary. If the GENEEC results indicate a potential concern, then the coupled PRZM and EXAMS models are used to refine the estimates of potential pesticide levels in surface water by including more pesticide-specific properties, simulating multiple years to reflect climatic variations, and modeling on a crop-specific basis. In comparison to GENEEC, PRZM/EXAMS includes more site-specific information in the scenario details regarding application method and temporal distribution with weather, and better accommodates chemical-specific parameters. However, it still uses the same 20-million liter pond, which represents a water body in an upland area from which few people would derive their drinking water. Thus, having a body of water which is more reflective of drinking water sources is an important revision to EPA's drinking water exposure assessment (see Section III.A.1).

2. Ground Water Screening Model

OPP developed SCI-GROW (Screening Concentration In GROund Water) as an initial screening model to estimate pesticide concentrations in ground water under reasonable, vulnerable conditions. SCI-GROW was developed by comparing selected pesticide properties to pesticide concentrations measured in ten prospective ground-water monitoring studies conducted by pesticide registrants. The studies were conducted by applying the pesticide at maximum allowed rates and frequency to hydrogeologically-vulnerable sites (i.e., shallow aquifers, sandy, permeable soils, and substantial rainfall and/or irrigation to maximize leaching). The highest three consecutive monthly data points from a selected well in each study were averaged to represent 90-day peak pesticide concentrations. A predictive equation, adjusted for the application rate, was developed by comparing the 90-day peak ground-water concentrations to a pesticide leaching potential index that is based on its persistence in soil (half-life) and affinity to adsorb to soil (soil-water partitioning coefficient).

Using data on pesticide persistence (in particular, soil metabolism half-life values) and soil adsorption, and the application rate, SCI-GROW estimates the concentration of a pesticide in shallow ground water (average depth 15 feet) beneath sandy, highly permeable soils. If the ground water estimates using SCI-GROW do not exceed the DWLOC, then OPP concludes that the pesticide is not expected to pose an unacceptable risk as a consequence of leaching into ground water and no further evaluation of ground water exposure is necessary. If the SCI-GROW results indicate a potential concern, OPP reviews available monitoring data for exposure refinement and, if necessary, requests additional information, usually in the form of prospective ground water monitoring studies.

D. EPA's Approach to Evaluating and Incorporating Drinking Water Monitoring Data into Human Health Risk Assessments

If the estimates of pesticide concentrations in drinking water from modeled surface-water sources (using GENEEC or PRZM/EXAMS) or ground-water sources (using SCI-GROW) do not exceed the DWLOC, then OPP concludes that the pesticide is not expected to pose an unacceptable risk via exposure to drinking water and no further evaluation is necessary. However, if any of the model estimates exceed the DWLOC, OPP gathers additional data in order to refine model estimates as well as available water monitoring data and uses these data to characterize the anticipated human exposure to the pesticide via drinking water. By the time a pesticide reaches this stage of review, OPP believes that the pesticide has some potential to reach surface water and/or ground water and that it has some potential to be present at levels of concern to human health.

Typical sources of monitoring data include USGS's NAWQA, NASQAN, and Toxic Substances Hydrology programs (USGS, 1998), EPA Office of Water's STORET database (US EPA OW, 1998), OPP's Pesticides in Ground Water Data Base (US EPA OPP, 1992), and the National Pesticide Survey (US EPA, 1990). OPP may also seek additional water monitoring data from open literature, state agencies, or other monitoring studies such as the Lake Erie Basin data collected at Heidelburg (OH) College, the Acetochlor Registration Partnership (ARP) study, and Novartis Crop Protection's Atrazine Volunteer Monitoring program.

The availability of adequate temporal and spatial monitoring data can reduce uncertainty associated with models, and can provide a more accurate estimate of the distribution of drinking water concentrations in areas of use. In a few cases, EPA will have considerable water monitoring data available for a particular pesticide, including registrant-sponsored monitoring studies and monitoring data from state, local and federal programs. Nevertheless, even when such data are available, they may have been collected in a manner that limits their usefulness for estimating the distribution of drinking water concentrations in areas of use. Therefore, EPA must exercise considerable judgement concerning the best use and interpretation of these data, and how to interpret exposures and risk estimates calculated from them. This is particularly true when trying to characterize exposures from a region where there may be more than one source of water monitoring data.

In evaluating, characterizing and interpreting water monitoring data, OPP scientists attempt to collect as much information as is readily available on the design of the studies. That is, OPP scientists try to determine how the samples were collected and analyzed, why they were collected, and where and when they were collected. To complete the FQPA assessment, OPP scientists review the reliability/validity of the monitoring data and present the range of values reported, the highest values reported, various return frequencies (e.g., 1 in 10 year concentration), and the mean and median values. If OPP has adequate data to produce a regional "picture" of the distribution of reported values, this is completed as well.

Because of the level of variability and uncertainty associated with existing monitoring data, the selection of a value or values to be incorporated into the human health risk assessment can be challenging. Sometimes valid reported values vary from one region to another by several orders of magnitude. Without having specific information on the history of the use of the pesticide in the sampled area, it is very difficult to fully understand the reasons for these differences. Interpreting the results of studies which include a large number of samples with no residues (i.e., "non-detects") poses additional difficulties. Non-detects can indicate that the pesticide of concern is not reaching the drinking water source. However, non-detects can also result when the samples are taken from areas where the pesticide is not applied or at times when the pesticide is not being used. Limitations with analytical methods may also result in non-detects (i.e., the pesticide may be present in the water at concentrations that are less than the limits of detection for the analytical method). For these reasons, the Agency must consider such information in interpreting non-detects in monitoring data sets. EPA often lacks data to verify that reported "non-detects" were in actual areas of use and, thus, has difficulty concluding that the pesticide, when used, is not in fact reaching water frequently enough to be of concern. Further, EPA is not always able to discern whether samples were taken from potential drinking water sources or waters that would be representative of such drinking water sources.

Despite the challenge of analyzing and interpreting these data, OPP will choose a value or values from valid monitoring data, when reliable data are available, to make decisions in the human health risk assessment. Values have been chosen from valid monitoring data even when the data were limited in time or location. As OPP has gained experience in reviewing and incorporating monitoring data into its risk assessments, it has generally chosen "reasonable, high-end" monitoring values. That is, OPP has selected a value on the "high end" (as defined in footnote 2) of the range rather than the highest measured value. This "high end" estimate is characterized in terms of its representativeness to drinking water sources and the degree of uncertainty present in the estimate. Such characterizations are used to determine the reliability of the estimate. While the ultimate goal of OPP is to estimate pesticide concentrations in tap water, such information (either in the form of monitoring data or of the effect of various water treatment processes on pesticide concentrations) is rarely available.

E. Workshops and Peer Reviews of Screening Models

OPP has sought and obtained external scientific review of its interim approach and of the models it uses to complete screening level assessments from both the FIFRA Scientific Advisory Panel (SAP) and expert panels convened by the International Life Science Institute (ILSI). Most of the external review to date has focused on evaluating the tools and methods used as initial screens to estimate pesticide concentrations in drinking water.

1. International Life Science Institute (ILSI) Risk Science Institute

OPP is working through ILSI to review its current model screening approach and to recommend improvements which could be implemented in the short term to improve the accuracy of its estimates. This cooperative effort is also evaluating how to refine screening level model estimates and how to use and interpret monitoring data. ILSI is an independent, nonprofit foundation established to advance the understanding of scientific issues related to nutrition, food safety, toxicology, and the environment. Through its Risk Science Institute, ILSI brings together experts from academia, industry, government, and public interest groups to address cutting-edge scientific issues. These expert groups meet in sessions open to the public and prepare reports for the Agency which are also distributed to the public. In October 1997, ILSI convened a working group of scientists with expertise in the fate, transport and occurrence of pesticides in surface water and ground water to evaluate OPP's tools and methods for estimating potential concentrations of pesticides in drinking water.

The ILSI working group concluded that (ILSI, 1998):

- Screening tools are needed to quickly identify pesticides and pesticide uses that are unlikely to contaminate drinking water AND that, in general, the screening models being used by OPP are of the appropriate type and level of detail to rapidly identify pesticides that are unlikely to occur in drinking waters above a level of concern;

- Preliminary evaluations indicate that these models are reliable for screening purposes. However, documentation and testing of the screening models against field observations is not yet sufficient to conclude that they will reliably meet this objective.

- The screening models should be improved so that non-problem pesticides (from a drinking water perspective) can be more accurately identified in the initial screen.

The ILSI working group provided recommendations on the types of information on drinking water needed to complete aggregate exposure assessments in its April 2, 1998, report, *Assessment of Methods to Estimate Pesticide Concentrations in Drinking Water Sources* (ILSI, 1998). The ILSI report advised that work toward developing probability distributions (as frequency of exceedance) for peak and long term average drinking water concentrations within a pesticide's use region(s) is needed. Ideally, the estimates of peak and long term average concentrations should be derived from full, temporal distributions in actual drinking water. These are the kinds of concentration data which are needed for inclusion with the more refined, probabilistic exposure assessments for residues on food performed using Monte Carlo analysis methods.

2. FIFRA SAP Review

In December 1997, OPP presented its interim methods for estimating exposure to pesticide residues in drinking water to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP). After commending OPP's work, the SAP encouraged OPP to develop a longer term plan for improving tools and methods to produce more refined and accurate estimates of drinking water concentrations. In response to specific questions from OPP, the SAP provided the following important comments:

- Many Panel members agreed that SCI-GROW generates appropriately conservative estimates of pesticide concentrations in drinking water from ground water sources for use in an initial screen. Most members believed the estimates need to be further tested and verified against monitoring data.

- Nearly all Panel members agreed that estimates produced by GENEEC are most likely overly conservative and that some adjustments should be made to account for the percent cropped area around a water body and the percent of that crop treated with the pesticide.

- Most Panel members considered PRZM/EXAMS a reasonable second tier modeling approach for refining estimates generated using GENEEC because of its use of more specific crop, weather, and site geophysical data and more extensive use of pesticide fate and transport data. However, as with GENEEC, many Panel members recommended incorporating an adjustment factor into the model for the percentage of cropped area within the reservoir drainage area. Additionally, the Panel was unanimous in recommending a rigorous effort to validate PRZM/EXAMS by (1) comparing model results with data from monitoring studies to determine the limitations and (2) performing a systematic sensitivity analysis of the model input parameters.

- The Panel stated that OPP needs to develop databases and methods that effectively use monitoring both in assessments and model validation. OPP should (1) invest time and resources in the development of geographic information system (GIS) tools related to soil type, crop coverage and water monitoring sampling points; (2) describe and document all variables in its models and methods, and better articulate the relative impact of these variables on its drinking water assessment; and (3) compare predictions from its screening models with monitoring data to better understand how these relate.

In July 1998, OPP presented to the SAP its proposed methods for basin-scale estimation of pesticide concentrations in flowing water and a proposal for using a reservoirs scenario in screening level assessments. The SAP commended OPP for developing a more realistic reservoir modeling scenario as an improvement over the "pond" scenario. Additionally, the SAP reacted favorably to the Agency's proposed strategy to develop a higher tier "watershed-scale" model for use in FQPA drinking water assessments. In response to specific questions from OPP, the SAP provided the following comments relative to the Index Drinking Water Reservoir and the Basin-scale Model Evaluation:

- The Panel overall agreed with the Agency on moving to a more "realistic" approach to estimating pesticide concentrations for use in drinking water assessments using the Index Drinking Water Reservoir (IDWR) scenario and agreed that the approach to the selection of the IDWR is reasonable. Several Panel members noted that location of treated fields in a watershed and soil/crop management factors are integral to potential reservoir contamination and should be considered in evaluating the IDWR approach.

- The Panel agreed that the Agency should move forward in utilizing the IDWR and encouraged the Agency to seek further scientific peer review as additional refinements are made. The Panel agreed that the proposed IDWR scenario is conservative even though the conditions of nearly 30 percent of the nation's reservoirs are likely to be more conducive to pesticide runoff than conditions around the chosen IDWR. This, they concluded, may be a result of poor reservoir design, thus, these systems may require special protection.

- Most Panel members concluded that the Agency's approach to evaluating basin-scale models was sound and the Panel listed five basic properties that should be considered in the model evaluation. The Panel viewed these models as a cost-effective means of providing information on pesticide concentrations in surface water given the complexities in monitoring water quality for a broad range of pesticides.

- Panel members were of the opinion that a single basin-scale model may not be sufficient to answer all the Agency's needs. Each model with its inherent strengths and weaknesses may be applicable to a subset of scenarios and, thus, the Agency may need several basin-scale models in its modeling suite for upper tier assessments. Additionally, the Panel agreed that the two monitoring data sets on which model performance will be evaluated are adequate for the initial evaluation. However, because a complete evaluation cannot be accomplished on two data sets, the Panel encouraged the Agency to continue to develop monitoring data to further evaluate basin-scale models.

In May 1999, OPP presented to the SAP a proposed approach for incorporating both a "crop area adjustment factor" and a drinking water reservoir scenario in the PRZM and EXAMS modeling. The Panel agreed that application of a "Percent Cropped Area" (PCA) factor "worked reasonably well with major crops in the Midwest and can be comfortably applied under those conditions." The SAP recommended that more consideration be given to low-cost, targeted monitoring, especially in the case of minor-use crops where modeling efforts tend to be imprecise. The Panel identified several limitations to the PCA approach:

- The PCA adjustment may underpredict chemical losses as some croplands contribute disproportionately to runoff (e.g., in a watershed with both row crops and forest, the cropland would contribute more significantly to runoff and watershed discharge and, in such instances, the model estimates may not be conservative enough).

- The PCAs were derived from hydrologic units which average over 1,000 square miles in size and county-based crop acreages, while most drinking water supplies are fed by smaller watersheds. The discrepancies between calculated PCA values and the PCA of the actual watershed surrounding a reservoir are likely to be more of a problem with minor crops than with major crops.

- The scale of the watershed does not allow certain factors such as landscape position, soil type, or slope to be taken into account. This may be important with minor crops that are not grown on the typical soil type modeled in the watershed.

- In the proposed approach, a single maximum PCA will be applied universally for a given pesticide across all regions and climatic zones while the model will use region-specific soil and climatic data. For consistency, the Panel recommended either choosing a single "worst case" scenario for a pesticide-crop combination by the county with the maximum PCA for a given crop or doing simulations with climatic and region-specific soil and PCA data.

Most Panel members agreed that the Agency should consider percent crop treated in future model refinements. The SAP noted that relatively high uncertainties may be encountered for chemicals which are applied to less than 10 % of the cropped area. One Panel member disagreed with the recommendation, commenting that the use of percent crop treated data moves beyond the original intent of the screening approach.

The May, 1999, SAP encouraged the Agency to continue to evaluate watershed-based models, as suggested by the July, 1998, SAP. The Panel recommended that the Agency consider watershed-based models in a GIS environment. While watershed-based regression models "may be appropriate and should be considered," the Panel cautioned that extrapolation of such model estimates to regions, times, and site conditions beyond the range under which the model was developed may provide inaccurate estimates.

III. POLICY CHANGES TO BE IMPLEMENTED

The long-term goal of OPP is to move toward the use of probabilistic drinking water exposure assessments for regulatory decisions under FQPA. That is, OPP wants to produce information on the number of people likely to be exposed to different levels of pesticide residues in drinking water and use this, along with information on the distribution of consumption values (i.e., the number of people who drink different amounts of water each day), to generate a probabilistic drinking water exposure assessment. OPP also wants to develop watershed-scale models for use in refined estimates of pesticide concentrations in drinking water when a screening level model estimate indicates a significant risk may exist. However, the Agency realizes how difficult it will be to accomplish both of these goals. Much remains to be done to develop adequate and reliable methods and the data necessary to use these approaches. In the meantime, OPP is considering refinements in its existing screening models and in its use of monitoring data for estimating concentrations of pesticides in drinking water.

Mathematical models allow OPP to rapidly screen pesticides to determine whether the Agency can confidently conclude that residues are unlikely to occur in drinking water at levels that will result in exceedances of the DWLOC (when combined with food and residential exposure) or whether the Agency needs more information to complete an assessment. The screening model estimates need to be protective to minimize the potential for "passing" a pesticide which may pose a concern while not being overly protective such that those pesticides which will truly pose no concern would fail the screen.

For drinking water assessments involving surface water, EPA will replace its current field pond scenario used in screening assessments with an "index" reservoir based on an actual drinking water reservoir (Section III.A.1). To more realistically reflect watershed-scale use, the model will also be adjusted for the percentage of the watershed feeding the reservoir that is actually in agricultural production (Section III.A.2). In the longer term, EPA will move to a watershed-scale model which more accurately captures basin-area processes and would be more appropriate for drinking water assessments (Section III.A.3).

One challenge facing the Agency is gathering enough reliable monitoring data to evaluate model estimates. EPA will continue to seek existing and new monitoring data to use in evaluating and strengthening its models. Results of a preliminary evaluation of PRZM/EXAMS model estimates against monitoring data presented to the FIFRA Scientific Advisory Panel (SAP) in May

1999[6] indicate that the surface-water screening models may not be consistent in overestimating pesticide concentrations. Comparisons made with limited monitoring data from the Midwestern U.S. that represent atrazine, simazine, and metolachlor concentrations in drinking water and on chlorpyrifos and simazine concentrations in rivers and streams in the San Joaquin River Valley of California showed that the highest values observed in monitoring fell below the crop-area adjusted estimated "high-end" (i.e., 1-in-10 year) peak (single day) concentrations. However, time-weighted annual average concentrations of atrazine in surface water sources of drinking water in one monitoring study exceeded the average annual model estimates, adjusted for the cropped area, in at least one year for five of 37 surface water sources. The modeled peak concentration of diazinon was equivalent (plus or minus a factor of 3) to peak monitoring results in the San Joaquin Valley, and only an order of magnitude greater than the lowest monitoring concentrations reported. A lack of extensive monitoring on diazinon in other use areas makes it difficult to determine whether the San Joaquin Valley data represent high-end or typical concentrations. A preliminary survey of eleven recent drinking water exposure assessments found that six screening model estimates resulted in predictions of pesticide concentrations of more than an order of magnitude greater than available monitoring data while five assessments resulted in model predictions that were similar to available monitoring data. These monitoring data represented either actual drinking water sources or water bodies that could be used as drinking water sources. The Agency is concerned that the differences between model estimates and monitoring data are uneven and not readily predictable.

The Agency plans to assess the capability of PRZM and EXAMS to provide high-end exposure estimates through (1) a sensitivity analysis of the models to determine what input factors most influence the model results and (2) a more thorough comparison of modeling and monitoring data to identify specific chemical, site, or use characteristics that could lead to inconsistencies in the modeling results. Results of the evaluation could determine whether, for certain pesticides or uses, revisions to the models are needed or whether another form of screening is necessary.

Reliable and representative data on measured pesticide residues in drinking water are a valuable assessment tool when available. However, because pesticide concentrations vary greatly in location (some drinking water sources are more vulnerable than others) and time (both seasonally and year-to-year), most existing monitoring data provide little more than a piece of a complex puzzle. OPP will continue to evaluate ways to better use existing monitoring data and seek options for obtaining additional monitoring data for pesticides that will allow for improved assessments of pesticide concentrations in drinking water.

A. Refinement of Screening Models for Use in Estimating Pesticide Concentrations in Drinking Water

OPP plans to continue using mathematical screening models as a part of its tiered

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[6] *Proposed Methods for Determining Watershed-derived Percent Crop Areas and Considerations for Applying Crop Area Adjustments to Surface Water Screening Models*; electronic copy available from the EPA home page under the Office of Pesticide Programs (OPP) at **http://www.epa.gov/pesticides/SAP/1999/may/pca_sap.pdf** .

approach to assessing the potential exposure to pesticides in drinking water in order to effectively focus resources on the potential problem chemicals. Further, modeling and other forms of extrapolation of data are the only assessment tools currently available to estimate potential concentrations of new pesticides. By October 31, 1999, EPA will make the following modifications to its approach in order to provide a more effective screen that identifies those pesticides for which a potential risk may exist.

1. The Use of An Index Drinking Water Reservoir in Surface Water Modeling Scenarios

In July, 1998, OPP presented to the FIFRA SAP a proposed "index" reservoir scenario to replace the "field pond" scenario currently used in its screening models (GENEEC and PRZM/EXAMS) to estimate pesticide concentrations in drinking water derived from surface water. OPP initially proposed to replace the existing farm pond scenario in drinking water screening assessments with Shipman City (IL) Lake because it was representative of a number of reservoirs in the central Midwest that are known to be vulnerable to pesticide contamination. These reservoirs tend to be small and shallow with small watersheds, and frequently have Safe Drinking Water Act compliance problems with atrazine, a herbicide widely used on corn grown in these watersheds. Shipman City Lake is 13 acres (5.3 ha) in area, averages 9 feet (2.7 m) in depth, and has a watershed area of 427 acres (178 ha) and a normal capacity of 144,320 m^3.

In July 1998, the FIFRA SAP called the approach to selecting index drinking water reservoirs reasonable, but also recommended additional scientific review and refinements[7]. OPP compiled and screened a list of 82 candidate reservoirs of varying sizes on the basis of the percentage of the watershed that is cropped (in this case, in corn), the ratio of drainage area to normal reservoir capacity, and the availability of monitoring data on corn herbicides. The initial list was trimmed to four reservoirs and the monitoring data and physical characteristics of these reservoirs were compared. After this evaluation, the Agency determined that the Shipman City Lake was still appropriate for use as an index drinking water reservoir. The index drinking water reservoir characteristics will be incorporated into the PRZM and EXAMS models and will be implemented in conjunction with percent cropped area adjustment (see Section III.A.2 for discussion of the Percent Cropped Area and for timing of implementation).

Estimates of pesticide concentrations in drinking water based on a Midwestern index drinking water reservoir may not be representative of residue levels in drinking water sources in other parts of the country. The modeling scenarios currently account for region-specific rainfall, soil, and hydrologic/runoff factors. The incorporation of an index drinking water reservoir is the latest step in an interim process that will eventually include basin-scale modeling. The Agency

[7] In public comments at the July 1998 SAP, one person expressed concern that Shipman City Lake was impacted by a point source (a pesticide loading facility), making it unsuitable for use as an index drinking water reservoir. In follow-up investigations, OPP determined that the loading facility was shut down and had not been in operation during the period that monitoring was conducted. Despite that potential concern, the SAP concluded that OPP could continue to develop the index drinking water reservoir using Shipman City Lake.

recognizes the need to develop scenarios for regional reservoirs for advanced tiers of modeling as well as for basin-scale modeling. However, this step is hampered by the lack of monitoring data outside of the Midwest that is of sufficient quality and extent to develop scenarios for additional reservoirs. As these data become available, EPA will develop and utilize regional reservoir scenarios in addition to the current index drinking water reservoir scenario.

2. Accounting for the Percentage of Area Cropped in the Index Drinking Water Reservoir Models

OPP has developed the necessary data bases and Geographical Information System (GIS) tools to enable it to consider the percentage of the area around the index drinking water reservoir that is cropped (i.e., the "Percent Cropped Area" or "PCA"[8]) and, thus, potentially treated with a pesticide when it uses its model to predict pesticide levels in a drinking water reservoir. OPP presented its plan for implementing the percent cropped area (PCA) as a refinement to the FQPA drinking water assessment process to the FIFRA Scientific Advisory Panel (SAP) in May 1999. The SAP agreed with the concept of the PCA as an "appropriate and reasonable" adjustment for major-use crops while still providing a protective (i.e., "highly vulnerable") assessment. It observed that the PCA "provides a technically defensible approach to reduce estimates of acute and chronic pesticide exposures to levels similar to those found in monitoring data." However, the SAP also identified several limitations to the approach, which have been outlined in Section II.E.2. [SAP Report No. 99-03C, May 27, 1999; available via the public docket].

Using 1992 Agricultural Census data, OPP ranked counties by PCA (since the data are reported on a county basis). For each crop, OPP used GIS tools to select the small watershed (the 8-digit Hydrologic Unit Code was the basis for evaluation) which has the highest PCA. PCAs were derived on a watershed basis in response to recommendations from the December 1997 SAP. The May 1999 SAP expressed concern that the Agency would be unable to validate PCAs for minor crops and recommended that EPA consider requesting low-cost, targeted monitoring data to evaluate pesticide contamination from use on minor crops [SAP Report No. 99-03C, May 27, 1999]. The May 1999 SAP also recommended that, for multiple crop use, the Agency could derive PCAs based on the maximum combined acreage of crops in a watershed. If pesticide application rate and timing vary from crop to crop, an aggregate pesticide concentration estimate could be made by separately simulating each crop in the watershed and then summing the individual model estimates. EPA plans to incorporate the SAP recommendations when it implements the PCA.

OPP will implement the "index" reservoir and percent crop area factors for the major-use crops presented to the May 1999 SAP[9] in its Tier 2 (PRZM/EXAMS) surface water screening

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[8] In the 12/22/98 draft science policy document, the crop adjustment factor was referred to as the "crop area factor" or "CAF." OPP has changed this term to "percent cropped area" or "PCA" to be more in line with the terminology used for "percent crop treated."

[9] The major-use crops and corresponding percent crop area adjustments (based on 8-unit HUC watersheds) presented at the May 1999 SAP are: corn (0.46), soybeans (0.41), wheat (0.56), and cotton

models by October 31, 1999. Once the Tier 2 model is in place, OPP will develop a Tier 1 index drinking water reservoir model, similar to that of GENEEC. Based on recommendations from the July 1998 SAP, PCAs will not be used with the Tier 1 model. The method for deriving watershed-based percent cropped area (PCA) correction factors will be converted into guidance for developing PCAs for major crops and cropping combinations through early 2000.

3. The Use of Watershed-scale Models

OPP completed and presented to the FIFRA SAP in July 1998 its preliminary evaluation of seven watershed-scale surface water models. Further efforts to evaluate these models against actual monitoring data are ongoing. This model evaluation effort is expected to provide an understanding of the relative accuracy of each of these models. OPP expects that one or more of these watershed-scale models will ultimately be used to produce more refined estimates of pesticide concentrations in drinking water. EPA is aware of the difficulties in developing and evaluating a watershed-scale model and is investing considerable effort in this area in FY2000.

4. Ground Water Screening Model Approach

OPP will continue to use SCI-GROW as an initial screening tool to determine the potential of a pesticide to contaminate ground water sources of drinking water at concentrations high enough to indicate a potential for risk. On the basis of recommendations of the FIFRA SAP in December 1997 and the experience of OPP in using SCI-GROW as an initial screen for drinking water assessments, OPP plans to systematically evaluate SCI-GROW against additional ground water monitoring data. Included in the evaluation will be an assessment of the potential limitations in the predictive capacity of SCI-GROW. For instance, do certain classes of chemicals or certain environmental fate parameters exist for which SCI-GROW is not well suited? Depending on the outcome of the assessment, some changes in OPP's approach to the initial screening tier for ground water may occur.

OPP also plans to evaluate models and develop a procedure for a second tier assessment of pesticides in ground water. The Agency has evaluated approximately fifty candidate models and has selected six models for detailed evaluation. OPP plans to use data from existing prospective ground water monitoring studies to evaluate the ability of the models to predict pesticide concentrations in ground water. To date, OPP has completed a preliminary evaluation with one data set. A similar evaluation with data sets from at least two other pesticides representing other crops, pesticide groups, use patterns and areas of the country is pending. As these evaluations are completed, the Agency intends to solicit external peer review and comment.

B. Use of Monitoring Data in Estimating Pesticide Concentrations in Drinking Water

The Agency believes its risk assessments would be strengthened by additional monitoring data and is working on a number of levels to fill in the gaps in monitoring data and acquire more

(0.20).

high quality data on pesticide concentrations in drinking water sources. At pesticide-specific levels, the Agency is requesting registrant-sponsored monitoring and runoff studies when screening models indicate a potential for concern. For multiple pesticides on the regional and national scales, the Agency is working with the U.S. Geological Survey (USGS) on a pilot reservoir monitoring study that will partially address missing data on pesticide concentrations in drinking water reservoirs. EPA is also exploring design considerations for a national survey of pesticides in drinking water with various government agencies and industry groups.

Currently, standardized guidance on assessing water monitoring data does not exist; the criteria for such assessments will depend on whether the data will be used for model validation or to make decisions on an individual pesticide. OPP does include valid monitoring data in its risk assessments. OPP does not always have information to determine whether the available monitoring data are representative of particularly vulnerable drinking water sources. The factors the Agency takes into account in evaluating the usefulness of the monitoring data in a risk assessment include distribution across the cropped region and pesticide use area, design and purpose of the study, vulnerability of the sites, representativeness of actual drinking water sources, monitoring of both source and treated water, sampling frequency sufficient to capture occurrence over time, analytical detection levels adequate to support aggregate analysis, and inclusion of important metabolites and degradates. A complete characterization of watershed, cropping patterns, pesticide application, water treatment, and water quality assist the Agency in interpreting monitoring results.

Some issues the Agency is attempting to address, based on its experience in evaluating existing monitoring data sets, include:

- Reliance on limited monitoring data (e.g., data that do not necessarily cover the range of use areas or span a sufficient time to capture seasonal and multi-year variations in pesticide concentrations) may lead to a decision that a pesticide does not pose a risk via the drinking water route under certain conditions when in fact it does under other existing conditions. Existing monitoring data may suggest that, on a national basis, the pesticide in question is not occurring in drinking water at a frequency of concern. However, in certain vulnerable areas, the pesticide may be found in concentrations high enough to be of toxicological concern.

- A monitoring data set may include non-detects, particularly in a national monitoring program. Non-detects may result when the pesticide occurs in concentrations that are below the limit of detection for the analytical method or when the pesticide is not present at all in the water sample. The absence of the pesticide in water may indicate that the pesticide is not likely to occur in drinking water sources; it may also result when samples are taken in areas where the pesticide is not used or during times of the year when the pesticide is not used. Information needed to evaluate the significance of non-detects is rarely included in the data set.

- The frequency of sample collection in monitoring studies is rarely adequate to capture peak pesticide concentrations or to estimate a reasonable maximum exposure.

- Concentrations of pesticide transformation products which are also of toxicological concern are rarely included in monitoring studies.

- Monitoring data based on untreated water samples do not account for removal or dilution of pesticides or, in some cases, the formation of more toxic compounds, that may occur in water treatment. However, because of the variability in treatment processes (which may include no treatment in the case of private wells), data gathered from treated samples may not be representative of minimal, typical or high-end treatment processes (see Section III.D).

- OPP intends to pursue data on distributions of pesticide concentrations in drinking water for use in aggregate and cumulative exposure and risk assessments from statistically-designed surveys that reflect: pesticide usage on a compound-specific basis, size of community water systems, water source, treatment (where warranted), system vulnerability to pesticide contamination, and temporal variability.

Developing criteria for evaluating monitoring data will not only aid in the evaluation of current data, but will help guide the design of future monitoring studies. As noted earlier, standardized guidance on assessing water monitoring data does not exist and will vary depending on how the data will be used. The Agency will be looking to various sources for guidance in assessing the usability of monitoring data in pesticide exposure assessments.

GIS tools, coupled with more detailed site, meteorological, and use characterizations, will also assist in characterizing and evaluating new and existing monitoring data. It will help the Agency assess potentially exposed populations and identify gaps in existing data in order to better target additional monitoring. The Agency continues to seek and develop such tools to improve its assessment of pesticide exposure from drinking water sources. At the same time, the Agency believes that more monitoring data, and more ancillary information (weather, site and usage characteristics), will be needed to take full advantage of the GIS capabilities at hand.

C. Drinking Water Vulnerability Assessments

The Agency will continue to seek and evaluate tools that would aid in assessing the vulnerability of water resources. Such tools would be useful not only in identifying areas of potential concern, but also in evaluating monitoring data and modeling estimates and in developing site selection criteria for surveys. Whether the drinking water assessment is conducted on a regional or national scale, the ultimate goal of such an assessment is to identify where the risk occurs since drinking water exposure is localized in nature. Vulnerability can be defined as the tendency or likelihood for contaminants to reach a surface- or ground-water system after introduction at some location within the watershed (National Research Council, 1993). Vulnerability depends on a combination of factors relating to pesticide usage, site/environmental factors, crop and pest management, and weather patterns. As noted in the National Research Council report, defining what constitutes "most vulnerable" is a challenge. Conceptual models of vulnerability exist, but differ in what is considered vulnerable and what factors are included.

Some factors affecting vulnerability of drinking water sources may differ for surface water and ground water. While a portion of the vulnerability assessment would be attributable to intrinsic site factors that can be mapped, other portions, such as weather patterns and management practices, are more dynamic and would require a different approach.

D. Accounting for Drinking Water Treatment Effects

The ultimate goal of the Agency is to conduct risk assessments for drinking water based on exposure to the consumer at the tap. However, differences of opinion exist as to how the Agency should address drinking water treatment effects in its drinking water assessment. The type and degree of drinking water treatment varies among community water systems. A significant portion of the nation's population consumes drinking water that is not treated with technology that is likely to reduce pesticide concentrations (i.e., private drinking water sources, community drinking water from ground water, or small surface water community systems). Private wells are likely to receive little or no treatment. The smaller community water systems will, at a minimum, add a disinfectant and may adjust the pH of the water, which may affect some classes of pesticides but not others. In some cases, the disinfectant treatment may result in transformation to a toxic degradate. Representatives of community water system operators have urged the Agency to focus its decision-making criteria on drinking water at the intake (source water) and consider the impact of pesticides on water entering drinking water supplies and private wells.

The Agency is in the process of gathering information on the extent of drinking water treatments in use and the effectiveness of these treatments on reducing the level of pesticides in water. Consideration of water treatment effects on pesticides in water must take into account not only effectiveness in pesticide removal, but also the secondary formation of any transformation products of toxicological concern as a result of the treatment process. The area and population served by the particular treatments, as well as temporal variations in drinking water treatment effectiveness, must also be considered. By the end of 1999, the Agency plans to issue a paper addressing how it will incorporate drinking water treatment effects in its drinking water exposure assessment. The public will be invited to comment on this science policy document.

E. Using Model Estimates and Monitoring Data in Quantitative Assessment of Uses of Concern for Drinking Water

In the Agency's experience, many pesticides pass the PRZM/EXAMS screen and no additional assessment is needed. In those instances where the model estimates suggest a potential for concern (i.e., the estimated pesticide concentration in water exceeds the drinking water level of comparison), additional steps taken by the Agency are determined on a case-by-case basis, depending on how much monitoring data are available and the extent of available information on use and management practices, which are pesticide-specific. These additional steps focus on gathering more information to reduce the uncertainty in the drinking water estimates or requesting additional monitoring data that can be related to drinking water sources. EPA plans to issue a paper, "Quantitative Assessment of Uses of Concern for Drinking Water," which will propose using available data and models to develop quantitative estimates of pesticide concentrations in drinking water for pesticides which EPA is particularly concerned and to estimate the potential size of the population exposed to these levels. This paper, which is expected to be released for public comment in the Spring of 2000, will describe how the Agency proposes to use these estimates in certain cases in quantitative aggregate human health risk assessments.

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THE AGENCY'S RESPONSES TO PUBLIC COMMENTS ON THE DRAFT FQPA SCIENCE POLICY DOCUMENT:

"Estimating the Drinking Water Component of a Dietary Exposure Assessment"
(Announced January 4, 1999; 64 FR 162; FRL-6054-8.)
(October 19, 1999)

The Agency reviewed all comments pertaining to this draft science policy document that were submitted specifically under this docket (OPP-00577) or in relation to the Tolerance Reassessment Advisory Committee (TRAC). At the end of the document is a listing of the names and affiliations of the individuals submitting comments. In revising the document, the Agency extensively reviewed and considered all comments. The comments addressed a broad range of issues and, in many instances, provided no general consensus. These differences in opinion highlight the difficulties the Agency faces in improving its existing science-based policy for estimating pesticide concentrations in drinking water. In addition, the Agency has incorporated comments from a May 1999 FIFRA Scientific Advisory Panel that evaluated the proposed approach for incorporating a crop area adjustment factor along with a drinking water reservoir scenario in its surface water screening models. The Agency grouped all comments according to the nature of the comment and the issue or section of the document which they addressed. For the substantive comments that follow, contrasting opinions are presented, along with EPA's response. The numbers used in the summary below correspond to specific commentors (listed at the end of this document).

A. Drinking Water As a Source of Dietary Exposure in Aggregate Exposure Assessments

Differences of opinion exist as to whether drinking water should even be considered in aggregate exposure assessments. One commentor [3] argued that drinking water should be considered as "other" nonoccupational exposure rather than as a "dietary" source of exposure and thus should only be included in aggregate exposure calculations when "reliable information" exists. Another commentor [1] agreed with the Agency position that drinking water is a dietary exposure source.

Agency Response: Ample data show that many pesticides can move from the site of application, by leaching, spray drift, and runoff, into surface water bodies or ground water that are used as sources of drinking water. In the case of some pesticides and some locations, a high potential exists for pesticide contamination of drinking water at levels of significance for public health. Therefore, OPP believes it is prudent to consider routinely the contribution to overall risk made by ingestion of drinking water. As for the issue of whether OPP should consider drinking water exposure as a dietary source of exposure, water is an important component of the human diet and as such should be considered for purposes of FQPA assessments as a dietary source of exposure.

B. Screening Approach For Drinking Water Exposure Assessments and the Conservative Nature of the Model Estimates

1. The Role of Screening Models

Philosophical differences were evident in the comments on the role and nature of screening models in drinking water exposure assessments. Some commentors [3, 7] felt that advanced model tiers should shift to more typical use scenarios that provide central tendency estimates (i.e., mean, mode or median values across all use sites, not just high-end exposure sites). However, other commentors [1, 6] felt that the Agency should focus on developing models that provide a "credible worst case scenario." One commentor [1] observed that the worst-case scenario is necessary because of uncertainties in pesticide runoff and leaching, and the absence of state or local management programs for mitigation. In noting that more realistic estimates do not necessarily equate to central tendency estimates, the commentor recommended that decisions based on screening models err toward obtaining more and better quality data on which to base a decision, and that models result in "realistic upper bound estimates" for protective decision-making. This commentor felt that conservatism (i.e., estimates of high-end exposure) in modeling is needed because it is unlikely that adequate monitoring data will be available to support registration or reregistration decisions in the near term.

Agency Response: The Agency uses a tiered approach to conducting drinking water assessments because this is a cost-effective way to factor drinking water exposure into risk assessments under FQPA. The initial screening tiers of the drinking water assessment process are purposefully designed to provide OPP with a high degree of confidence that pesticides which are cleared will not in fact pose a drinking water concern. However, an initial screen that is too "fine" results in wasted Agency review resources. Accordingly, OPP's goal is to minimize the potential for "passing" a pesticide which may pose a concern while not being overly cautious such that those pesticides which will truly pose no concern fail the screen. In order to achieve this goal, OPP considers pesticide concentrations from a high-end exposure scenario rather than a central-tendency scenario which, by nature, approximates a middle level of exposure. As defined in the draft science policy document, "high-end" refers to a combination of events and conditions such that, taken together, produces conceivable risk greater than that estimated to be experienced by 90 percent of the population, but less than the maximally exposed risk[10]. The Agency's approach to refining estimates of pesticide concentrations in drinking water in higher tiers is to reduce the uncertainties in the estimate, which often requires obtaining more and better quality data with which to make a decision.

2. The Conservatism of the Screening Models

Commentors disagreed on the conservative nature of surface water screening models. Some [3, 7] felt that the existing screening models generally overestimated pesticide concentrations, sometimes by several orders of magnitude. They recommended that the models be calibrated with "representative monitoring data" to ensure that the degree of conservatism is "understood, recognized, and reasonable." However, other commentors [1, 6] questioned the

[10] "High-end" is defined in "Guidelines for Exposure Assessment," FR Vol. 57, No. 104, May 29, 1992, and "Guidance on Risk Characterization for Risk Managers and Risk Assessors." F. Henry Habicht II, Deputy Administrator, U.S. EPA, to Assistant and Regional Administrators, U.S. EPA, Feb. 26, 1992.

assumed conservatism of the existing models without more data to support the assessment. One commentor [1] noted that pesticide detections at some water treatment plants, resulting in exceedances of MCLs and installation of additional treatment measures, suggest otherwise.

Agency Response: As is explained earlier is the response to Question B1, OPP's goal is to minimize the potential for "passing" a pesticide which may pose a concern while not being overly cautious such that those pesticides which will truly pose no concern fail the screen. In order to achieve this goal, OPP considers pesticide concentrations from a high-end exposure scenario rather than a central-tendency scenario which, by nature, approximates a middle level of exposure. Although OPP believes that its screening level approach achieves this goal, recent work to compare model estimates to monitoring data is informative as to whether model estimates grossly overestimate pesticide concentrations in surface water. The Agency completed a preliminary evaluation of PRZM/EXAMS model estimates against monitoring data for the index reservoir / percent crop area modeling revisions presented to the FIFRA Scientific Advisory Panel (SAP) in May 1999[11]. Initial comparisons were made with limited monitoring information on atrazine, simazine, and metolachlor in the Midwestern U.S. and on chlorpyrifos, simazine, and diazinon in the San Joaquin River Valley of California.[12] For simazine and metolachlor in the midwest, the highest values observed in monitoring fell below the crop-area adjusted estimated "high-end" (i.e., 1-in-10 year) one-day and average annual concentrations. For atrazine, the crop-area adjustment still resulted in estimated 1-in-10-year peak concentrations greater than most monitoring peaks. A number of time-weighted annual average concentrations from the ARP monitoring sources (5 of the 37 reservoirs) exceeded the crop-adjusted average annual estimates in at least one year of the study. In the San Joaquin Valley, the crop-adjusted model estimates of 1-in-10 year peak concentrations for chlorpyrifos and simazine were greater than the highest observed monitoring concentrations by a factor or two or more. In the case of diazinon, however, the estimated peak concentrations were in the same range as monitoring results, and lower than four monitoring values. The confidence in the comparison between peak monitoring and modeling values is low because the low sampling frequencies in the monitoring studies were not adequate to capture peak concentrations.

In the May 1999 SAP presentation, OPP presented a preliminary survey of eleven recent

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[11]*Proposed Methods for Determining Watershed-derived Percent Crop Areas and Considerations for Applying Crop Area Adjustments to Surface Water Screening Models*; electronic copy available from the EPA home page under the Office of Pesticide Programs (OPP) at **http://www.epa.gov/pesticides/SAP/1999/may/pca_sap.pdf** .

[12] Monitoring data for the midwestern U.S. included the 37 drinking water sources for which untreated water was sampled in the Acetochlor Registration Partnership (ARP) (see the EPA OPP home page at **http://www.epa.gov/oppefed1/aceto/index.htm** for more information) and 76 midwestern reservoirs sampled by USGS (Scribner et al. 1996. Concentrations of selected herbicides, herbicide metabolites, and nutrients in outflow from selected midwestern reservoirs, April 1992 through September 1993. U.S. Geol. Surv. Open-File Report 96-393. Prepared as part of the Toxic Substances Hydrology Program. Laurence, KS.). Monitoring data for the San Joaquin valley came from USGS's NAWQA program, from 14 sites sampled in 1993 and 1994.

drinking water exposure assessments.   In six of those assessments, screening model estimates with PRZM and EXAMS, using the farm pond scenario and assuming 100% of the drainage area is in crop and is treated with the pesticide at the same time, resulted in predictions of pesticide concentrations of more than an order of magnitude greater than available monitoring data. However, in five assessments, the model predictions were similar to available monitoring data (assuming that the monitoring data captured the true peak concentration). The Agency has some concern that the differences between model estimates and monitoring data are uneven and not readily predictable.

The SAP [SAP Report No. 99-03C, May 27, 1999] noted that model inconsistencies could come from many sources, including inaccurate process representation in the model itself (preferential flow, ground water discharge, etc.), quality of input data (soil, climate, chemical use, etc.), quality of monitoring data (sampling frequency, duration of study, etc.), and differences in the size of the modeled watershed versus the size of the watersheds in which the data was collected. They concurred with the steps identified by the Agency to assess the capability of the model to provide high-end exposure estimates, including a sensitivity analysis of the models to determine what input factors most influence the model results and a more thorough comparison of modeling and monitoring data to identify specific chemical or scenario characteristics that could lead to inconsistencies in the modeling results. Results of the evaluation could determine whether, for certain pesticides or uses, corrections to the models are needed or whether another form of screening is necessary. OPP is in the process of completing a sensitivity analysis and these results should be available within the next 6 months.

3. Steps Beyond the Screening Tiers

Two commentors [3, 5] expressed concern that the draft science policy document lacked a discussion of refinements beyond the initial screening tiers or a "clear definition of procedures for making science-based risk decisions when reliable information is not available or is insufficient for purposes of refining the screening level estimates of pesticide exposure through drinking water."

Agency Response: The initial science policy document spelled out the general screening approach and identified areas where more information or tools are needed. In the Agency's experience, many pesticides pass the tier 2 screen and no additional assessment is needed. In those instances where the model estimates suggest a potential for concern (i.e., the estimated pesticide concentration in water exceeds the drinking water level of comparison), additional steps taken by the Agency are determined on a case-by-case basis, depending on how much monitoring data are available and the extent of available information on use and management practices, which are pesticide-specific. These additional steps focus on gathering more information to reduce the uncertainty in the drinking water estimates or requesting additional monitoring data that can be related to drinking water sources.

EPA plans to issue a paper, "Quantitative Assessment of Uses of Concern for Drinking Water," which will propose using available data and available models in certain circumstances to develop quantitative estimates of pesticide concentrations in drinking water and to estimate the potential size of the population exposed to these levels.   OPP believes that it needs to be able to develop such estimates in those cases where all available data and information present a compelling case that a pesticide has a very high probability of resulting in significant human health risks through the drinking water pathway. This paper, which is expected to be released for comment in early 2000, will describe how the Agency proposes to use these estimates in certain cases in quantitative aggregate human health risk assessments.

4. The Suitability of Screening Models for Drinking Water Exposure Assessments

Opinions regarding the suitability of screening models for drinking water assessments varied. One commentor [3] noted that screening models are reliable for showing a lack of concern about drinking water exposure, but cannot show that a certain level of exposure is likely. Another [6] thought that the FQPA provision of "reasonable certainty of no harm" should put the burden on the registrant to show a reasonable certainty of no harm rather than on the Agency to show a reasonable certainty of harm. This commentor proposed that the Agency first look at existing monitoring data; if any value exceeds the drinking water level of comparison (DWLOC), then EPA cannot conclude a reasonable certainty of no harm. If no value exceeds the DWLOC, then EPA should move to screening models.

Agency Response: Under FIFRA and FFDCA, the ultimate burden of proving safety of a given pesticide rests on the proponent of a FIFRA registration (or reregistration) of the pesticide or the proponent of establishing or maintaining a FFDCA tolerance or exemption. The draft science policy document explains the approach that EPA will use for factoring drinking water into tolerance decisions under FQPA. The policy document is not intended in any way to address or alter the burden of proof as established by existing statutes and court decisions. As for looking at monitoring data as the first screen and then proceeding to models, the Agency relies on models as the first screen because monitoring data are not always available and the data that are available require considerable scientific judgment and time to evaluate their suitability. Issues related to the evaluation and interpretation of monitoring data are elaborated upon in a later section of this comment/response paper. The screening model approach allows for an effective use of the Agency’s limited resources.

C. Scale of the Drinking Water Assessment

Commentors [3, 6, 7] provided different reasons for why a complete national assessment of the drinking water contribution to aggregate exposure from a pesticide was not always necessary. One [3] stated that aggregate exposure assessments should be done on a regional, not national, scale. A second [7] recommended that EPA begin on the local scale, with high vulnerability/high pesticide use areas representing the “worst-case.” If the local scenario indicates potential concerns from pesticide exposure in drinking water, EPA would proceed to a regional scale incorporating more watersheds. Regional or national scales would be more appropriate for probabilistic drinking water assessments. A third commentor [6] stated that if EPA anticipates, or if existing data show, some portion of the population will consume pesticides in drinking water at a level greater than the DWLOC, then the Agency cannot conclude that a reasonable certainty of no harm exists and a broader, national assessment will not change that conclusion. This commentor recommended that EPA focus its assessment not to protect "most" people or an "average" child, but to protect those who are most likely to be exposed to the highest levels of pesticides in tap water.

Agency Response: The Agency's goal in conducting a drinking water assessment is to identify where risk from the drinking water pathway will occur and the magnitude of the risk (including the number of people exposed above levels of concern from a human health perspective) from this pathway of exposure. If the severity and magnitude of exposure is significant enough from this pathway (that is, exposure is expected to significantly impact a significant subpopulation), then this exposure would be factored into the aggregate exposure assessment for tolerance setting purposes. Since drinking water exposure is localized in nature, determining the severity and magnitude of risk from drinking water exposure requires evaluation at the watershed scale and then estimation of the number of watersheds and people exposed at larger scales (e.g., regional and national). One approach is to evaluate the potential exposure at vulnerable locations and use the results of this evaluation to extrapolate to other locations.

Vulnerability can be defined as the tendency or likelihood for contaminants to reach a surface- or ground-water system after introduction at some location within the watershed[13]. Vulnerability depends on a combination of factors relating to pesticide usage, site/environmental factors, crop and pest management, and weather patterns. As noted in the National Research Council report, defining what constitutes "most vulnerable" is a challenge. Conceptual models of vulnerability exist, but differ in what is considered vulnerable and what factors are included. Some factors affecting vulnerability of drinking water sources may differ for surface water and ground water. While a portion of the vulnerability assessment would be attributable to intrinsic site factors that can be mapped, other portions, such as weather patterns and management practices, are more dynamic and would require a different approach. The Agency will continue to seek and evaluate tools that would aid it in assessing the vulnerability of water sources. Such tools would be useful not only in identifying areas of potential concern, but also in evaluating monitoring data and modeling estimates.

D. Sources of Pesticide Contamination Not Considered

One commentor [6] observed that the assessment approach did not account for additional exposure sources from non-agricultural uses of pesticides, such as pesticide use in urban and suburban areas, which have been found to be significant sources of contamination in the U.S. Geological Survey (USGS) monitoring studies, or exposure from mixing/loading or storage areas.

Agency Response: The Agency is aware that non-agricultural uses of pesticides can contribute to pesticide concentrations in water but, for the most part, lacks the tools to estimate the extent of contributions for many non-agricultural uses, especially home uses. To the extent

[13] *Ground Water Vulnerability Assessment : Predicting Relative Contamination Potential under Uncertainty* / Committee on Techniques for Assessing Ground Water Vulnerability, Water Science and Technology Board, Commission on Geosciences, Environment, and Resources, National Research Council, 1993.

possible, EPA uses available monitoring data to evaluate the impact of non-agricultural pesticide use on water quality. However, where monitoring data are absent or of limited scope, the Agency can provide only a qualitative assessment of the impact of non-agricultural use of pesticides on drinking water. In these instances, the Agency will often require additional data, including monitoring studies, in order to make an assessment of the non-agricultural contributions of pesticide contamination to drinking water sources. The Agency also note this type of limitation in its drinking water exposure assessments.

E. Implementation of the Index Reservoir (IR) in Surface Water Screening Models

1. Replacing the Farm Pond With an Index Reservoir

Most of the commentors [1, 2, 3, 5, 6, 7] expressed concern with the Agency's plan to replace the current farm pond with an index reservoir in its tier 2 surface water screening model. However, their reasons for concern differed. Two commentors [1, 6] were concerned that the index reservoir would not be representative of highly vulnerable reservoirs while other commentors [2, 3, 5, 7] were concerned that the index reservoir would be biased toward sites which have unreasonably high vulnerability. Two [3, 7] disagreed with the Agency's assessment that the index reservoir would provide more realistic estimates of pesticide concentrations in surface water for the following reasons:

- an increased ratio of treated area to water volume will increase estimated concentrations;
- no clear relationship exists between drainage area to reservoir normal capacity (DA/NC) and concentration;
- the assumption that the treated fields are adjacent to the reservoir does not account for spatial distribution, buffering effects, or agronomic/management practices;
- drift is not likely to contribute significantly to pesticide levels in larger bodies of water and should be eliminated from the model.

Agency Response: The reservoir parameters chosen were similar to a number of small reservoirs located in intensively cropped areas in the Midwestern United States. The Agency evaluated actual monitoring data to select a site that represented a "high-end" site in terms of concentration of pesticides in the reservoir. In so doing, the Agency believes that it has selected a site that is representative of vulnerable reservoirs but is not unreasonably vulnerable.

The ratio of watershed area to volume used for the index reservoir is based on parameters from an actual reservoir. Since the Agency plans to use the index reservoir in combination with the percent cropped area, the ratio of cropped watershed area to volume will decrease for virtually all uses. Indeed, model scenario comparisons presented in the May 1999 SAP report and the July 1998 SAP report[14] show this to be the case.

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[14] *Proposed Methods for Basin-Scale Estimation of Pesticide Concentrations in Flowing Water and Reservoirs for Tolerance Reassessment*; electronic copy available from the EPA OPP home page at **http://www.epa.gov/pesticides/SAP/1998/index.htm#october** .

Two commentors referred to data presented for 13 selected reservoirs in the July 1998 SAP report to make their case that no relationship exists between DA/NC and pesticide concentration. The Agency's assessment of the DA/NC - concentration relationship was based on an evaluation of all the reservoirs included in the Acetochlor Registration Partnership (ARP) study, which is monitoring 175 surface water sources of drinking water from the corn-growing region of the midwest east to Pennsylvania and Delaware[15]. When all reservoirs are considered, higher pesticide concentrations in water tended to be associated with the larger DA/NCs. The 13 reservoirs selected for further consideration were those considered to be vulnerable based on monitoring data and do not represent the full range in pesticide concentrations or DA/NCs.

The current Tier 2 surface water model is not capable of accounting for the spatial distribution of cropping patterns, pesticide use, or location of water bodies within a watershed. The Agency anticipates that a watershed-scale model, when it becomes available, would be able to account for spatial distribution of crops in the drainage basin. Buffers and management practices are not always specified on the label nor consistently implemented in the field, making it difficult for the Agency to include them in the modeling scenario. If specific buffers or management practices are included in the pesticide label, these additional factors are addressed by EPA in its characterization of the risk posed by the pesticide or in further model refinements, if warranted.

The spray drift contribution to a larger water body is influenced by factors such as size and geometry of the water body, location of the treated field in relation to the receiving reservoir and streams which flow into the reservoir, and will be reevaluated. While the contribution by pesticide drift to drinking water residues is likely to be lower for a reservoir than that for the farm pond, the Agency does not believe it should be ignored altogether. The Agency plans to use the Spray Drift Task Force data on spray drift to determine an appropriate estimate of drift loading to the index reservoir. EPA also plans to evaluate drift loading in the watershed-scale model evaluations. This work is currently in progress.

2. Appropriateness of Using Small Reservoirs

One commentor [3] questioned the appropriateness of small reservoirs, arguing that they are generally more prone to local factors, especially cropping patterns and pesticides used, that "have little or no relevance to national exposures, even for the 99th percentile." However, two commentors [1, 6] were concerned that the index reservoir, coupled with cropping adjustments, may not be "truly representative of high risk scenarios." None of the commentors provided concrete evidence to support their concerns.

Agency Response: The Agency disagrees that an assessment based on a small reservoir which may be prone to local factors has "little or no relevance" to the estimation of drinking water exposure for purposes of aggregate risk assessment under FQPA. The intent of the screening model is to determine whether estimated high-end pesticide concentrations in drinking

[15] More information on the ARP study is available from the EPA OPP home page at **http://www.epa.gov/oppefed1/aceto/index.htm** .

water could exceed a DWLOC. If, as available monitoring data seem to indicate, the estimates based on EPA's index reservoir represent a high-exposure scenario, then the Agency can conclude with confidence that the pesticide does not pose a concern nationally if the screening model estimates are below the DWLOC. If, however, the estimates are similar to or greater than the DWLOC, then the model estimates indicate a potential concern. Whether a significant subpopulation would be exposed to concentrations of concern would depend on how frequently those conditions would be expected to occur nationally. Arguably, some number of identifiable communities of 25 people or more could be viewed as a significant subpopulation from a drinking water perspective.

Available monitoring data seem to indicate that the index reservoir does represent a high exposure scenario. The index reservoir was selected from the 175 surface water sources of drinking water included in the ARP study. The study is biased toward vulnerable watersheds in intensive corn-growing regions, although it also includes larger bodies of water (including the Great Lakes), flowing water, and reservoirs in less intensively cropped areas. Thus, Shipman City Lake, the selected index reservoir, is ranked 8th of the 175 surface water sources of drinking water (95th percentile) in terms of concentration of atrazine, from a group of reservoirs located in an intensive pesticide use region of the country.

3. Representativeness of the Midwestern Index Reservoir

Several commentors [2, 3, 7] questioned whether a midwestern index reservoir, which applies primarily to corn, would be representative outside the Midwestern U.S. Two commentors [3, 7] recommended a series of "representative" reservoirs for each geographic region and/or crop. They asserted that advanced (tier 2) screening models should incorporate region-specific parameters (crop area factors, rainfall, watershed size, soil and watershed variations, etc) to provide "more realistic concentrations" than Tier 1 screening models.

Agency Response: The Agency agrees that estimates of pesticides in drinking water based on the index reservoir may not be as accurate for other parts of the country as they are for Midwest locations. However, the modeling scenarios currently do account for region-specific rainfall, soil, and hydrologic/runoff factors. The incorporation of an index reservoir is the latest step in an ongoing effort to improve EPA's drinking water risk assessments that will eventually include basin-scale modeling. The Agency recognizes the need to develop regional reservoirs for advanced tiers of modeling as well as for basin-scale modeling. However, this step is hampered by the lack of monitoring data outside of the Midwestern U.S. that are of sufficient quality and extent to develop scenarios for additional reservoirs. As these data become available, EPA will develop regional reservoir scenarios to go with the current index reservoir.

The Agency is using what it believes to be a vulnerable reservoir scenario in a screening model to determine whether a potential concern exists. If the model, when used in other regions, shows pesticide concentrations in water at or above levels of concern, then region-specific factors will be considered in further refinements. The refinements may include targeted monitoring in areas where the pesticide is used. In its comments to the Agency's May 1999 report, the SAP recommended that "more consideration should be given to low-cost, targeted monitoring, especially in the case of minor-use crops where modeling efforts tend to be imprecise" [SAP Report No. 99-03C, May 27, 1999].

4. Peer Review and Calibration of the Index Reservoir Model

Two commentors [3, 7] opposed adopting the index reservoir until the percent crop area (PCA) is available and the model is "properly calibrated with reliable and representative monitoring data." They urged peer review of the model, with further presentation to the SAP and stakeholder groups before adoption. Indeed, several commentors [1, 2, 3, 6, 7] urged the Agency to compare model predictions to available monitoring data for calibration. Some commentors [2, 3, 7] felt that model calibration/validation was essential before the index reservoir is used for regulatory purposes. They also recommended that the model predictions be calibrated against alternate models such as the regression-based Surface Water Mobility Index (SWMI) developed by Novartis Crop Protection, Inc., and the American Crop Protection Association (ACPA) [3, 7]. Other commentors [1, 6] felt an evaluation of model predictions against monitoring data is essential to determine whether the assumptions will include the most highly exposed populations and whether the index reservoir "is truly representative of high risk scenarios."

Agency Response: The Agency presented methods to derive watershed-based cropping area adjustments to the SAP in May 1999 and plans to implement the index reservoir in conjunction with a crop area adjustment. The SAP generally supported the Agency's tiered approach for drinking water assessments, including the use of a percentage crop area adjustment coupled with the index reservoir. The Agency agrees that peer review and extensive model evaluation are needed and continues with efforts to do so. The SAP presentations referred to in this comment/response document and in the drinking water science policy paper are part of this continuing process. In the interim, EPA is tasked with completing drinking water assessments as part of FQPA and is doing them with what it believes to be the best tools available. Comparisons of model estimates with monitoring data were done in evaluating the index reservoir and percent cropped area adjustments [July 1998 and May 1999 SAP reports] and will continue as additional monitoring data are obtained. The Agency feels that the index reservoir and percent cropped area modifications are an improvement over existing modeling approaches and, for that reason, is moving forward with those changes.

The Agency disagrees with the recommendation to calibrate one model against another. In particular, OPP has concluded that SWMI is not considered a valid model for concerns that are addressed in the later section on Watershed- or Basin-Scale Modeling (Section G).

F. Accounting For the Percent Cropped Area in Surface Water Screening Models

1. Use of a Percent Cropped Area (Cropped Area Factor)

Comments were divided on the use of a correction factor to account for the area of the watershed that is planted to a specific crop or crops of concern [referred to as the Crop Area Factor (CAF) in the initial science policy document, the term has been changed to Percent Cropped Area (PCA) to be more in line with the Percent Crop Treated terminology already in use in the Agency]. Two commentors [3, 7] agreed with the approach while two others [1, 6] questioned whether the PCA approach would represent a "highly vulnerable" system. One commentor [1] warned against selecting a factor that represented the "average" crop mixture in a watershed, noting that drinking water treatment is "challenged" where cropping is intense, best management practices are inadequate or not applied, precipitation events carry recently-applied pesticides to streams, and multiple pesticide applications are made. Another commentor [6] encouraged the Agency to conduct a "nationwide review of data" to determine whether PCA-adjusted model estimates capture high-exposure scenarios before applying the factor to screening model results.

Agency Response: Since submitting its initial science policy document for public comment, the Agency presented its plan for implementing the percent cropped area (PCA) as a refinement to the FQPA drinking water assessment process to the FIFRA Scientific Advisory Panel (SAP) in May 1999. The SAP agreed with the concept of the PCA as an "appropriate and reasonable" adjustment for major-use crops while still providing an effective initial screen (i.e., one that provides EPA with a high degree of confidence that "cleared" pesticides will in fact not pose a significant risk of exposure through the drinking water route). The Panel observed that the PCA "provides a technically defensible approach to reduce estimates of acute and chronic pesticide exposures to levels similar to those found in monitoring data." However, the SAP also identified several limitations to the approach and, particularly for assessments involving minor-use crops, recommended that the Agency consider requesting "low-cost, targeted monitoring" and field experiments using rainfall simulators and other techniques to evaluate pesticide loss under extreme rainfall conditions. Such information would improve the Agency's ability to predict pesticide concentrations in water and increase the amount of data available to evaluate models [SAP Report No. 99-03C, May 27, 1999].

2. Percent Cropped Treated

Two commentors [3, 7] recommended that the Agency go beyond the Percent Cropped Area (PCA) approach to use "product-specific area factors" (e.g., percent crop treated) when market share information is available.

Agency Response: The use of percent crop treated is limited by the availability of data at a sufficiently detailed scale in order to determine pesticide use distribution within a watershed. Currently, only two states (California and New York) collect pesticide usage data at such a detailed scale. The Agency is concerned that incorporation of percent crop treated would compromise the protective nature of the screening models. A national average percent crop treated would not be appropriate, since it does not reflect the variation in percentage of crop treated across the country (i.e., while in some watersheds, the percentage of crop treated may be less than the national average, in other watersheds, it may be much greater). Such an adjustment would also need to account for temporal changes in pesticide usage resulting from changes in pest pressures, management practices, and alternate treatments. As model improvements are made and as more and better quality monitoring and pesticide usage data become available nationwide, the Agency may consider such adjustments in the future for advanced tier refinements in a basin-scale model.

The majority of the May 1999 SAP agreed that the Agency should consider percent crop treated in future model refinements. The Panel advised OPP to analyze the existing New York and California data to determine the extent of discrepancy between "percent crop area" and "percent crop treated" and then "make an educated decision on how to handle this issue." The SAP noted that relatively high uncertainties may be encountered for chemicals which are applied to less than 10 % of the cropped area. One Panel member disagreed with the recommendation, commenting that the use of percent crop treated data moves beyond the original intent of a screening approach. Use of this data would increase the site-specificity of the technique and may not appropriately represent a worst-case scenario for screening purposes. In its presentation to the May SAP, the Agency illustrated the effect of the percent crop treated adjustment for diazinon in the San Joaquin Valley. This adjustment reduced the screening model estimates to a value that was an order of magnitude lower than the peak concentrations detected in the NAQWA monitoring data.

3. Technical Comments on PCA Implementation

Additional comments related to the specifics of deriving and implementing the PCA factor included using county-based rather than watershed-derived PCAs [3], determining PCAs for minor-use crops [7], and accounting for more than one crop use in a watershed [3, 7]. One commentor [3] encouraged the Agency to use county-based PCAs because they were readily available. Another commentor [7] noted the challenges in deriving and validating PCAs for minor crops and recommended that the Agency either (1) validate PCAs with major crops and extrapolate to minor crops, or (2) use a default PCA reflective of minor crop status. Recommendations for accounting for pesticide use on more than one crop in a watershed focused on weighting for crop area and accounting for temporal differences in application [3, 7].

Agency Response: In December 1997, the SAP recommended that, since the Agency is assessing a watershed process, it develop PCAs on a physiographically-based unit (i.e., watershed boundary) rather than on a political unit (i.e., county boundary). This recommendation was supported by the latest SAP in May 1999. The May 1999 SAP also expressed concern that the Agency would be unable to validate PCAs for minor crops because of a lack of monitoring data for evaluation and recommended that EPA consider requesting low-cost, targeted monitoring data to evaluate pesticide contamination from use on minor crops [SAP Report No. 99-03C, May 27, 1999].

For multiple crop use, the May 1999 SAP recommended that the Agency could derive PCAs based on the maximum combined acreage of crops in a watershed. If pesticide application rate and timing vary from crop to crop, an aggregate pesticide concentration estimate could be made by separately simulating each crop in the watershed and then summing the individual model estimates. EPA plans to incorporate the SAP recommendations when it implements the PCA.

G. Watershed- or Basin-Scale Models

In general, the commentors [1, 3, 7] supported the Agency's plan to develop watershed-scale models, but were not aware of any validated watershed-scale models currently in existence.

These commentors noted the complexity of factors involved in watershed-scale modeling as well as the difficulty in developing such a model. In addition to the models the Agency discussed in the July 1998 SAP report, two commentors [3, 7] recommended using a regression-based model such as the Surface Water Mobility Index (SWMI) developed by Novartis Crop Protection, Inc., a pesticide registrant, and the American Crop Protection Association (ACPA), the pesticide industry trade association, because "it is based on real monitoring data that reflect all relevant landscape factors."

Agency Response: The Agency generally agrees with these comments; OPP wants to develop watershed-scale models for use in refined estimates of pesticide concentrations in drinking water when a screening level model estimate indicates a potential risk may exist. As noted earlier, the Agency intends to shift its resources toward developing watershed- or basin-scale modeling and away from further refinements in its screening approach/method. A validated, mechanistic basin-scale model will address many of the concerns that arise from applying field-scale models, such as PRZM, to basin-scale assessments. EPA is aware of the difficulties in developing and evaluating such a model, and expects that a usable basin-scale model is several years away. In commenting on the Agency's May 1999 presentation on its proposed method for incorporating the percent cropped area into surface water models, the SAP expressed the opinion that PRZM is not the model to use if the Agency is seeking to develop a representative watershed or basin configuration. However, the SAP also noted that addressing the limitations in the current modeling process will require "considerable investment of resources."

The SAP encouraged the Agency to continue evaluating other models as suggested in the July 1998 SAP report, especially watershed-based models in a GIS environment. The Panel noted that watershed-based regression models could be developed with increasing availability of high-quality data, but that extrapolation to areas, times, and conditions beyond the range of available data may provide inaccurate estimates [SAP Report No. 99-03C, May 27, 1999]. Similar concerns about the transportability of the regression models beyond the range of the data set used for development were expressed in the December 1997 SAP response[16].

The Agency previously reviewed and commented on the SWMI model developed by Novartis and ACPA[17]. While the data set used for model development (Lake Erie Basin data collected by Baker and others at Heidelburg, OH, College) is one of the more complete pesticide data sets for the Midwest, the Agency is concerned about the ability to use this model on a national scale for a number of reasons. The model is a regression based on data collected from a

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[16] FIFRA Scientific Advisory Panel report on *A Set of Scientific Issues Being Considered by the Agency in Connection with Estimating Drinking Water Exposure as a Component of the Dietary Risk Assessment*; electronic copy available from the EPA OPP home page at **http://www.epa.gov/pesticides/SAP/1997/december/finaldec.pdf** .

[17] A May 7, 1999, memo (Review Comments on "A Simple Regression Model for Predicting Surface Water Concentrations Resulting from Agricultural Field Runoff and Erosion") from Parker, Hetrick, and the Water Quality Tech Team, through Joe Merenda, EFED Director, to Keefer, Gilding, and the ACPA Drinking Water Exposure Workgroup provided detailed comments on the SWMI model.

limited geographic region (six watersheds in Ohio). Pesticide concentrations reported in monitoring studies from other geographic areas are frequently an order of magnitude or more higher than the concentrations measured in the Lake Erie basin. Thus, the Lake Erie basin data may not necessarily reflect the more vulnerable watersheds of the region. This becomes a major concern since a regression-based model, unlike a mechanistic model, is limited to the geographical and temporal boundaries of the data set.

H. Ground Water Screening Models

1. SCI-GROW

Two commentors [3, 7] expressed an opinion that SCI-GROW is an appropriate tool for screening in "highly vulnerable" shallow aquifers, but recommended further "verification" with existing monitoring data to establish the range in pesticide properties over which the model would be reliable.

Agency Response: The December 1997 SAP recommended that OPP fully document and publish SCI-GROW, characterize uncertainties in the estimates, and determine the likelihood of false negatives in a SCI-GROW screen. The Agency plans to complete documentation of the SCI-GROW model by the end of 1999. Once completed, the documentation will be published as recommended by the SAP. Further steps involve evaluating the model against other monitoring data to improve and expand the current range in pesticide properties over which the model can provide predictions and to subject the model to an internal and external peer review and evaluation process.

2. Tier 2 Ground Water Model

Two commentors [3, 7] urged the Agency to develop a higher tier model capable of predicting "more realistic pesticide concentrations in drinking wells." Another commentor [1] recommended incorporating decision criteria into the "more complex" screening models to distinguish four management options:

- register and provide a tolerance
- conditionally register and provide a tolerance
- deny registration pending additional information
- deny registration

Agency Response: The Agency plans to develop a tier 2 ground water model after it completes work on SCI-GROW. Although no tier 2 model currently exists for ground water, the Agency requests additional information, usually in the form of prospective ground water monitoring studies, when SCI-GROW results in estimated concentrations of pesticides in ground water that exceed the DWLOC.

The initial science policy document was intended to provide a framework to describe how science will be used in doing drinking water assessments. It was not intended to address management options, such as the registration triggers suggested by one commentor. Such decisions take into account a broader range of factors, of which the scientific data are one part.

I. Probabilistic Drinking Water Assessments

1. Development of Probabilistic Models

One commentor [3] noted that because drinking water varies locally, a probabilistic approach to drinking water exposure assessment must incorporate a geospatial distribution based on monitoring and/or modeling. Much remains to be done to develop “adequate and reliable probabilistic methods” and the necessary data for these methods. Moreover, the commentor encouraged OPP to work with other offices in the Agency (Office of Research and Development and Office of Water) as well as other government agencies and stakeholder groups to develop the necessary tools and data. OPP must first determine that it has “reliable information on the distribution of exposure to a pesticide via drinking water on a national or regional basis” [3].

<u>Agency Response</u>*:* While the long-term goal of the Agency is to use probabilistic drinking water exposure assessments for tolerance assessments under FQPA, the tools and data for performing probabilistic assessments are not yet available. Since pesticide concentrations vary both in time and in location, a probabilistic approach for drinking water exposure assessments will be more valuable if it can incorporate spatial and temporal distributions. However, at this point the Agency has only limited information on the spatial and temporal distributions in pesticide concentrations and would have to make numerous non-verifiable simplifying assumptions for distributions that are not available.

2. Potential Conflict of Interest

In the draft document, the Agency noted that it was working cooperatively with the International Life Science Institute (ILSI) to advance the development of probabilistic drinking water assessments. One commentor [6] raised a concern about a potential conflict of interest with ILSI, which "has an economic interest in pesticide regulations, and is governed by the very industry EPA is charged with regulating. EPA's reliance on ILSI for advice here violates the Federal Advisory Committee Act and the Agency's own conflict of interest requirements."

<u>Agency Response</u>*:* ILSI is an independent, nonprofit foundation established to advance the understanding of scientific issues related to nutrition, food safety, toxicology, and the environment. Through its Risk Science Institute, ILSI brings together experts from academia, industry, government, and public interest groups to address cutting-edge scientific issues. These expert groups meet in sessions open to the public and prepare reports for the Agency which are also distributed to the public. EPA's cooperative, open and public relationship with ILSI neither presents a conflict of interest nor a violation of the Federal Advisory Committee Act.

J. Interpreting and Using Monitoring Data in Drinking Water Assessments

1. Adequacy of Existing Monitoring Data

Differences of opinion exist on the quality and quantity of existing monitoring data available to the Agency and how these data should be incorporated into drinking water exposure assessments. While one commentor [3] believed “the science and technology, including monitoring databases, exist to develop and support realistic risk assessment tiers for drinking water, beyond the preliminary screening tiers” and pushed for use of monitoring over modeling, another [1] said that the Agency would need to rely on modeling because monitoring data adequate to support registration decisions is unlikely to be available in the near term. Some commentors [3, 7] felt that the Agency does not use monitoring data as much as it could while another [6] recommended that EPA abandon the approach of relying on data that may not be representative of especially vulnerable water sources.

Agency Response: As noted in the draft science policy document, the Agency gathers available monitoring data for use in the drinking water exposure assessment for a pesticide if the screening model estimates are close to or exceed the drinking water level of comparison (DWLOC). The science policy document listed typical sources of monitoring data used by the Agency. Commentors [3, 7] mentioned additional sources, such as Lake Erie Basin data collected at Heidelburg (OH) College, the ARP study, and Novartis’ Atrazine Volunteer Monitoring program. The Agency is aware of and uses these data sources, as well as others, in its assessments. To help interpret the monitoring data, the Agency gathers as much information as it can on where and when the samples were collected, the circumstances surrounding the collection, how the samples were collected and analyzed, sample locations in relation to pesticide usage, timing of samples in relation to time of pesticide application in the sample area, nature and size of the water body, and size and characteristics of the area draining into the water body.

The quantity and quality of data varies from pesticide to pesticide. Even the data sources mentioned above are limited in geographic extent (primarily in the Midwestern U.S.) and in time. Therefore, the Agency’s decision to use monitoring data involves consideration of many factors and each judgment is case-by-case. In some instances, the monitoring data does not provide helpful or adequate information to characterize reasonable high-end exposures.

2. Evaluating Monitoring Data

Several commentors [3, 7] urged the Agency to develop “clear, formal guidance” on how monitoring data is evaluated for usefulness and to use “all monitoring data available and meeting predefined quality criteria” for drinking water exposure assessments. Although none of the commentors provided specific criteria for evaluating monitoring data, several [1, 3, 6, 7] identified factors that need to be considered, including distribution across the cropped region and pesticide use area, design and purpose of the study, vulnerability of the sites, representativeness of actual drinking water sources, monitoring of both source and treated water, sampling frequency sufficient to capture occurrence over time, analytical detection levels adequate to support aggregate analysis, inclusion of important metabolites and degradates, and complete characterization of watershed, cropping patterns, pesticide application, water treatment, and water quality. One commentor [3] referred to an upcoming ILSI report on the amount of sampling needed to address local, regional, and national assessments.

Agency Response: The Agency agrees that developing criteria for evaluating monitoring data will not only aid in the evaluation of current data, but will help guide the design of future monitoring studies. Currently, standardized OPP guidance on assessing water monitoring data do not exist; the criteria for such assessments will depend on whether the data will be used for model validation or estimating drinking water exposures for a single pesticide. The Agency will be looking to the ILSI report and to other sources for guidance in assessing the usability of monitoring data in pesticide exposure assessments. OPP plans to develop interim guidance during FY2000.

3. Use of Geographical Information Systems (GIS)

One commentor [3] urged the Agency to take advantage of Geographic Information System (GIS) tools in evaluating monitoring data.

Agency Response: The Agency believes that GIS tools, coupled with more detailed site, environment, and use characterizations, will assist in characterizing and evaluating existing monitoring data. GIS tools will also help the Agency assess potentially exposed populations and identify gaps in existing data in order to better target additional monitoring. The Agency continues to seek and develop such tools to improve its assessment of pesticide exposure from drinking water sources. At the same time, the Agency believes that more monitoring data, and more ancillary information (site and usage characteristics), will be needed to take full advantage of the GIS capabilities at hand.

4. Additional Monitoring Data Needs

Commentors [1, 3, 6, 7] noted that additional monitoring is needed for pesticides on a number of scales. While one commentor [7] felt the gaps should be filled with "government sponsored monitoring programs" targeted at drinking water sources, another [1] noted that conditional registrations with monitoring provisions will be necessary to obtain the data. A third commentor [3] urged the Agency to grant "sufficient time" to allow for collection of new monitoring data "of sufficient quality to refine screening level estimates."

Agency Response: The Agency is working on a number of levels to fill in the gaps in monitoring data and acquire more high quality data on pesticide concentrations in drinking water sources. At pesticide-specific levels, the Agency is requesting registrant-sponsored monitoring and runoff studies when screening models indicate a potential for concern. On regional and national scales involving multiple pesticides, the Agency is working with the U.S. Geological Survey (USGS) on a pilot reservoir monitoring study that will fill in missing data on pesticide concentrations in drinking water reservoirs. EPA is also discussing design considerations for a national pesticide in drinking water survey with various government agencies and industry groups. Such efforts cannot rely solely on "government sponsored monitoring programs."

5. Treatment of High-End Monitoring Data

In addition to differences in what is considered "adequate and reliable" monitoring data for use in drinking water assessments, commentors disagreed on how the monitoring data should be used. One commentor [6] stated that EPA should not “arbitrarily” discard the highest reported values from monitoring, but use them in the assessment if they represent “real world” monitoring data for drinking water. However, another commentor [7] recommended using high-end monitoring data points only as “upper-bound” estimates for screening purposes, but not quantitatively in aggregate exposure/risk assessments.

Agency Response: There is no simple rule regarding whether using or excluding high-end monitoring data values is appropriate for risk assessments. The Agency evaluates the monitoring data in relation to accompanying information on spatial and temporal distribution of the sample points, the water body (or bodies) represented by the sampling, the characteristics of the site surrounding the water body, and the weather/environmental conditions represented by the study. EPA also attempts to determine whether the sampled water bodies represent real or likely drinking water sources and whether the data represent potentially vulnerable sites (as noted earlier, the concept of vulnerability is not a simple, easy-to-define concept). If the evaluation indicates that the data do represent drinking water sources, then such data may be used quantitatively in aggregate exposure assessments.

6. Non-Detects

Several recommendations were made regarding interpreting non-detections in monitoring data sets [3, 6, 7]. One commentor [6] notes that non-detects in monitoring data can be misleading and should be considered only in light of the concerns listed in the science policy document. Another commentor [7] recommends that the Agency confirm and “validate” non-detects in the same manner as detects. If non-detects are from areas where the product is not used, the commentor recommends reporting the value as 0; if the non-detects are in areas of use, report the value as as one-half of the limit of detection (LOD) or quantification (LOQ). This commentor encouraged the development of statistical “imputation methods” to define the shape of data distributions below LOD/LOQ.

Agency Response: Non-detects can indicate that the pesticide of concern is not reaching the drinking water source. However, non-detects can also result when the pesticide is analyzed in areas where or times when the pesticide is not being used. Limitations with analytical methods may also result in non-detects. All of these factors will influence how the Agency interprets non-detects in monitoring data sets. This information, particularly on pesticide usage in relation to the monitoring sites, is not always available for the pesticide monitoring data provided to the Agency, thus making it difficult to interpret the meaning of some reported non-detects. The Agency does not believe that it is appropriate at this time, given the current state of monitoring data and ancillary information, to establish a policy such as that which has been applied to non-detects on food (i.e., to assume that a pesticide is present at ½ the LOD whenever a non-detect is reported).

K. Considering Water Treatment Effects in Drinking Water Assessments

Two commentors [3, 7] stated that the Agency should always consider treated, or "finished," water in its drinking water assessments, if such data are available, since this represents the actual exposure to the population. Both encouraged EPA to develop default pesticide reduction factors by evaluating effects of drinking water treatment on pesticide concentrations and effectiveness variability among plants. Another commentor [6] cited statistics showing that a "large number" of people consume drinking water that is not treated (17% of the nation uses private drinking water sources which are not usually treated; roughly half of drinking water comes from ground water, which is generally not treated with technology that is likely to reduce pesticide concentrations; "large numbers" of drinking water facilities do not use modern technology which would "substantially" reduce pesticide concentrations) to support the position that EPA should not focus on the effectiveness of drinking water treatment in pesticide exposure assessments.

A commentor representing a number of community water system operators [1] recommended that an appropriate default treatment should be "the minimum treatment allowed by federal regulations governing public water supplies and private wells." For ground water supplies, this would be equivalent to no treatment; for community surface water systems, this would be disinfection only (e.g., chlorine) for some systems, or conventional treatment (rapid mix-coagulation-flocculation-sedimentation-filtration-disinfection) which covers the majority of surface water systems in the U.S. [1] However, this commentor urged the Agency to focus its decision-making criteria on drinking water at the intake (source water) and consider the impact of pesticides on water entering drinking water supplies and private wells.

<u>*Agency Response*</u>*:* The Agency is in the process of gathering information on the extent of drinking water treatments in use and the effectiveness of these treatments on reducing the level of pesticides in water. Consideration of water treatment effects on pesticides in water must take into account not only effectiveness in pesticide removal, but also the secondary formation of any transformation products of toxicological concern as a result of the treatment process. The area and population served by the particular treatments, as well as temporal variations in drinking water treatment effectiveness, must also be considered. The Agency plans to issue a paper addressing drinking water treatment effects in its drinking water exposure assessment in early 2000.

L. Use of the Drinking Water Level of Comparison (DWLOC) in Aggregate Exposure Assessments

1. Consistency in DWLOC and MCL Approaches

Two commentors [1, 6] felt that OPP's DWLOC was not consistent with the Office of Water's Maximum Contaminant Level (MCL) and the Safe Drinking Water Act (SDWA) standard-setting process. They urged OPP to establish enforceable standards that support source water protection and drinking water program compliance with pesticide standards. One commentor [8], noting that the DWLOC procedure uses the Reference dose (RfD) as the maximum daily intake, requested that the document clarify that this is a conservative approach since the true safe level is some value above the RfD.

Agency Response: The MCL established by the Office of Water is a regulatory standard based on the RfD that also takes into consideration such factors as what is technologically achievable in terms of contaminant removal and the costs associated with such removal. The DWLOC does not factor in such economic/technology-based considerations. Moreover, in practice the DWLOC is a "tool" that OPP uses in its human health aggregate risk assessment process to identify pesticides which require further evaluation and more sophisticated assessments. The DWLOC is an expression of the allowable level of a pesticide in drinking water which when combined with food exposures will not result in exposure above an acceptable level of risk. OPP strongly supports the need to prevent drinking water contamination and has available to it federal authority to control pesticide use and application methods to mitigate contamination of water.

2. Current Approach For Determining the DWLOC

In the draft document, the Agency asked for comment on its current approach of calculating DWLOCs for drinking water exposure after contributions from food and residential sources have been considered. Responses to this question were divided. Two commentors [6, 7] called the approach reasonable, although one [7] said the process is only as valid as the dietary and nondietary assessments. If the assessments "grossly overestimate risk," then the DWLOC is not really a level of concern. One commentor [1] saw "no clear logic to making calculation of exposure through drinking water contingent on the contributions from food and residential exposure" and recommended that all routes of exposure should be considered equally. Another commentor [3] stated that total aggregate exposure should not depend on the order in which the potential routes of exposure are considered. This commentor expressed concern that current risk evaluation procedures for the three routes of exposure are "at vastly different levels of development" and encouraged the Agency to develop more sophisticated risk refinement methods for all important routes of exposure.

Agency Response: The DWLOC was originally designed as a tool to be used along with screening level estimates of pesticide concentrations in drinking water to determine the need for more sophisticated analyses of aggregate exposure. In many cases the comparison of the DWLOC to the screening level drinking water estimate has allowed EPA to cost-effectively clear the pesticide from the perspective of total aggregate risk. Commentors raise a very legitimate issue, however, with regard to the approach that the Agency takes to mitigation or additional monitoring requirements in those cases where the DWLOC is met or exceeded and further refinements in the drinking water estimate of exposure still do not allow the pesticide to be cleared from an aggregate risk perspective. It would seem that a regulatory approach which would have as its objective the identification of the most cost-effective method for reducing aggregate risk (taking into consideration all pertinent regulatory authorities–SDWA as well as FIFRA and FFDCA and perhaps even relevant State and local regulatory authorities) would be the preferable approach.

List of Public Commentors and Affiliations

I.D. # *Name and Organization*

1. John H. Sullivan, Deputy Executive Director, *American Water Works Association.* Denver, Colorado.

2. Arthur L. Craigmill, Extension Toxicity Specialist, *Extension Toxicity Network (EXTOXNET), University of California*. Davis, California.

3. FQPA Implementation Working Group (IWG). IWG is a non-governmental coalition of farm, food, pest management, and manufacturing organizations.

4. Sam Moore, President, *Kentucky Farm Bureau Federation.* Louisville, Kentucky.

5. Jack Laurie, President, *Michigan Farm Bureau.* Lansing, Michigan.

6. Erik D. Olson, Senior Attorney, *Natural Resources Defense Council (NRDC).* Washington, D.C.

7. Dave Whitacre, Vice President, Development, *Novartis Crop Protection, Inc.* Greensboro, North Carolina.

8. Elaine Francis, Director, *Pesticides, Toxics and Multimedia Staff, Office of Science Policy, Office of Research and Development, U.S. Environmental Protection Agency.* Washington, D.C.

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